DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 24,2014

Collagen Matrix, Inc.
Ms. Gloria Zuclich
Senior Manager of Regulatory Affairs
15 Thornton Road
Oakland, New Jersey 07436

Re: K142496
Trade/Device Name: Collagen Dental Membrane - Conformable IIBP
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: II
Product Code: NPL
Dated: September 04, 2014
Received: September 05, 2014

Dear Ms. Zuclich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142496

Device Name: Collagen Dental Membrane – Conformable IIBP

Indications for Use:

Collagen Dental Membrane - Conformable IIBP is intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

1. Application Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355
Contact Person: Gloria Zuclich
Senior Manager of Regulatory Affairs
Date of Summary: November 24, 2014

2. Name of the Device

Device Trade Name: Collagen Dental Membrane – Conformable IIBP
Device Common Name: Collagen Dental Membrane
Device Classification Name: Barrier, animal source, intraoral
21 CFR 872.3930
Product Code NPL
Device Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Dental Membrane IV
K090216

Tutodent® Dental Membrane
CopiOs™ Pericardium Membrane
K073097

4. Description of the Device

Collagen Dental Membrane – Conformable IIBP is a non-friable, resorbable membrane matrix consisting of purified intact collagen tissue derived from bovine pericardium. The membrane device is flexible and conforms to the contours of the defect site. Collagen Dental Membrane – Conformable IIBP is supplied pre-hydrated, sterile, non-pyrogenic, and for single use only.

The collagen dental membrane has a thickness of approximately 0.3 to 1.0 mm and is available in the following sizes 15 x 20 mm, 20 x 30 mm, and 30 x 40 mm.

5. Intended Use

Collagen Dental Membrane - Conformable IIBP is intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic

treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

6. Summary/Comparison of Technical Characteristics

Collagen Dental Membrane - Conformable IIBP and its predicates have similar technological characteristics. In particular, Collagen Dental Membrane - Conformable IIBP is substantially equivalent to Collagen Dental Membrane IV with regard to design and function. The bovine pericardium collagenous tissue material is also purified in the same manner as the bovine dermis collagenous tissue of Collagen Dental Membrane IV device. Collagen Dental Membrane – Conformable IIBP and Tutodent® Dental Membrane and CopiOs™ Pericardium Membrane are similar in design and function and utilize the same source of animal tissue, i.e. bovine pericardium.

A comparison between the subject and predicate devices is shown in the following table.

Parameter	Collagen Dental Membrane –Conformable IIBP (This submission)	Collagen Dental Membrane IV K090216	TutoDent® / CopiOs™ K073097
Indications for Use	Intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.	Intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.	Intended for use in oral surgical procedures as a resorbable material for augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.
Material	Intact purified collagen tissue	Intact purified collagen tissue	Intact purified collagen tissue
Collagen Source	Bovine pericardium	Bovine dermis	Bovine pericardium
Form	Membrane	Membrane	Membrane
Color	White to off-white	White to off-white	White to off-white
Physical Integrity	Non-friable	Non-friable	Non-friable
Sizes	15 x 20 mm 20 x 30 mm 30 x 40 mm	15 x 20 mm 20 x 30 mm 30 x 40 mm	15 x 20 mm 20 x 30 mm 30 x 40 mm
Thickness	Approx. 0.5 mm	Approx. 0.5 mm	Not tested
Conformability	Conformable to defect site	Conformable to defect site	Conformable to defect site
Suture Strength	Can be sutured	Can be sutured	Can be sutured
Porosity	Semi-permeable; permeable to nutrients and macromolecules	Semi-permeable; permeable to nutrients and macromolecules	Semi-permeable; permeable to nutrients and macromolecules
Cross-linked	Yes	Yes	No
Method of Crosslinking	Proprietary	Proprietary	Not applicable

Parameter	Collagen Dental Membrane –Conformable IIBP (This submission)	Collagen Dental Membrane IV K090216	TutoDent® / CopiOs™ K073097
Resorption Time/In Vivo Stability	Gradual resorption, resorbed in approximately 16 weeks as demonstrated in animal testing	Gradual resorption, 6-9 months target	Gradual resorption, resorbed in approximately 8 to 16 weeks as demonstrated in animal testing
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
How Supplied	Pre-hydrated	Dry, with hydration prior to implantation	Dry, with hydration prior to implantation
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
Single Use/Reuse	Single use only	Single use only	Single use only
Packaging	Double peel package	Double peel package	Double peel package

Nonclinical Tests Submitted

The substantial equivalence of Collagen Dental Membrane – Conformable IIBP and its predicates was demonstrated based on *in vitro* characterization studies, biocompatibility studies, *in vivo* animal studies, and clinical history of the predicate devices.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate devices. A series of bench tests were conducted which included an evaluation of physical properties such as membrane thickness, conformability, suture strength, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature.

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess safety of the Collagen Dental Membrane-Conformable IIBP as an implantable material. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	Test Method/ Model	Results
Cytotoxicity	ISO Agarose Overlay Method, ISO 10993-5	Non-cytotoxic. No evidence of causing any cell lysis or toxicity.
Sensitization	ISO Guinea Pig Maximization Sensitization Test, ISO 10993-10	No evidence of sensitization was observed. The test article was not considered a sensitizer. The test article extract met the requirements of the test.
Intracutaneous Reactivity	Acute Intracutaneous Reactivity in Rabbit, ISO 10993-10	No erythema and no edema from the test extract injected intracutaneously into the rabbits. The test article extract met the requirements of the test.
Acute Systemic Toxicity	ISO Systemic Toxicity in Mice, ISO 10993-11	No mortality or evidence of systemic toxicity. The test article extract met the requirements of the test.
Pyrogenicity	USP Pyrogen Study – Material Mediated, ISO 10993-11	Non-pyrogenic. The test article extract met the requirements of the test.
Genotoxicity	In Vitro Mouse Lymphoma Assay, ISO 10993-3	None of the test article treatments induced substantial increases in the number of revertant colonies. Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic. The test article extract met the requirements of the test.

Test	Test Method/ Model	Results
Genotoxicity	Bacterial Mutagenicity Test – Ames Assay, ISO 10993-3	Non-mutagenic to *Salmonella typhimurium* strains TA97a, TA98, TA100, and TA1535 and to *Escherichia coli* strain WP2-uvrA. The test article extract met the requirements of the test.
Implantation	Subcutaneous Implantation in Rats	Minimum tissue reaction up to 4 weeks of implantation and no adverse tissue reaction to the host.
Subchronic/ Chronic Toxicity	Subcutaneous Implantation in Rats	Minimum tissue reaction up to 24 weeks of implantation and no adverse tissue reaction to the host.

In addition to the *in vitro* characterization tests, animal studies using a rabbit intra-oral model, as well as a rat subcutaneous model were conducted to evaluate the *in vivo* stability and local tissue response to the subject device.

Viral inactivation studies were performed to ensure the viral safety of the product.

Clinical Test Submitted

Given the similarities between Collagen Dental membrane – Conformable IIBP and the predicate devices, it was determined that a clinical study would not be necessary to demonstrate substantial equivalences.

7. Conclusion of Non-clinical Studies

The results of the in vitro product characterization and biocompatibility testing, as well as the animal study show that Collagen Dental Membrane-Conformable IIBP is as safe and substantially equivalent to the identified predicate devices.